

Claims 10-13, as filed, and claim 9 as amended, are pending in the application. All grounds of rejection have been overcome by amendment or argument.

Claim 9 was rewritten as an independent claim, which contains all limitations from original claim 1 (now cancelled), but removes the objected to term "substantially."

2. 35 U.S.C. §112, 2nd paragraph rejection.

Claims 1-22 were rejected under 35 U.S.C. § 112 2nd paragraph, but only claims 1 and 2 were specifically rejected as being indefinite. Applicants have cancelled claims 1 and 2 and therefore, the rejections of said claims are moot. Furthermore, applicants respectfully request that the 35 U.S.C. § 112 2nd paragraph rejections of the pending claims be clarified or withdrawn.

3. 35 U.S.C. § 103(a) rejection.

Claims 9-13 stand rejected under 35 U.S.C. §103(a) as being obvious over Thosar (6,410,054) in view of Blume, et al (U.S. Patent No. 4,526,777) or Thosar in view of Putter (U.S. Patent No. 4,834,982.) While the Applicants do not

agree with the Office's conclusion, the conclusion is irrelevant because Thosar is not prior art to the instant application under 35 U.S.C. § 103(c).

The Manual of Patent Examining Procedure discusses rejections under 35 U.S.C. § 103(c) and points out that:

[e]ffective November 29, 1999, subject matter which was prior art under former 35 U.S.C. 103 via 35 U.S.C. 102(e) is now disqualified as prior art against the claimed invention if that subject matter and the claimed invention "were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person."

Manual of Patent Examining Procedure, Eighth Edition, Section 706.02(1)(1).

The subject application was filed on May 11, 2001 and has an earliest priority date of May 12, 2000 based on U.S. Provisional Application No. 60/203,637. Therefore, the subject application qualified under § 103 (c).

Thosar issued on June 25, 2002, which is after the earliest priority date of the instant application, and therefore, Thosar does not qualify as a prior art reference under 35 U.S.C. §§ 102 (a) or (b) but can only be considered as prior art under 35 U.S.C. §§ 102 (e). Thus, if the rejection is proper, it must be one under §§ 102(e)/103.

Thosar and the instant application were, at the time the subject matter of the claimed invention was made, subject to an obligation of assignment to the same person. Applicants have attached herewith a copy of the assignment record for the instant application indicating assignment to Pharmacia Corporation. Thosar, as shown on its face, is assigned to G. D. Searle & Co., which was bought out by Pharmacia Corporation. Since the instant application and Thosar are subject to an assignment to the same entity, Thosar is disqualified as prior art under § 103(c) and the rejection should be withdrawn.

Blume et al. alone cannot support a § 103 rejection of claims 9-14. Blume is directed towards "novel pharmaceutical composition having effective combined diuretic and antihypertensive properties while also being capable of resisting or reversing hypokalemia." Column 1, lines 11-14. Blume does not disclose or suggest combining delayed release aldosterone antagonists, such as eplerenone, with an antihypertensive agent, as is claimed in the instant application. Consequently, one of skill in the art who read the Blume reference would not have a reasonable expectation of success in preparing the instant invention. Therefore, the Applicants respectfully request

that the 35 U.S.C. § 103 rejection based on Blume be withdrawn.

Putter et al. alone cannot support a § 103 rejection of claims 9-14. Putter is directed towards "to diuretically active composition of matter composed of triamterene and furosemide, the furosemide being in a controlled release form in order to facilitate solubilization thereof in triamterene micelles." Column 1, lines 15-19. Putter does not disclose or suggest combining delayed release aldosterone antagonists, such as eplerenone, with an antihypertensive agent, as is claimed in the instant application. Consequently, one of skill in the art who read the Putter reference would not have a reasonable expectation of success in preparing the instant invention. Therefore, the Applicants respectfully request that the 35 U.S.C. § 103 rejection based on Blume be withdrawn.

CONCLUSION

Applicants respectfully submit that all requirements of patentability have been met. Allowance of the claims

and passage of the case to issue are therefore respectfully solicited.

Should the Examiner believe a discussion of this matter would be helpful, he is invited to telephone the undersigned at (312) 913-2114.

Respectfully submitted,

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Version marked to show changes made.

9. A pharmaceutical composition for administration to a subject mammal exhibiting a diurnal cycle of plasma aldosterone concentration having an acrophase, the composition comprising a therapeutically effective amount of a delayed-release formulation of an aldosterone antagonist drug which, when orally administered about 6 to about 12 hours prior to the acrophase, provides a profile of plasma drug concentration corresponding to the diurnal cycle of plasma aldosterone concentration, wherein [The] the composition [of Claim 1 that] further comprises a second formulation comprising a therapeutically effective amount of a second antihypertensive agent.